NEW YORK UNIVERSITY SCHOOL OF MEDICINE

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

Dear Sirs:

I understand that the FDA proposes to regulate some types of allograft as medical devices. This decision may significantly hinder patient treatment.

Each year, I perform about 125 neurosurgical procedures in which allograft is used. In many of these patients, more than one piece of allograft is used. Since starting my neurosurgical practice five years ago, I have observed a greater than 98% fusion rate using allograft, similar to the best reported rates for autograft. More importantly, the patients prefer allograft since use of this bone rather than autograft significantly reduces postoperative pain. In addition, use of allograft allows earlier mobilization and shorter hospital stays. I have not seen a single complication or infection related to the use of allograft.

The use of allograft significantly helps many patients, and I hope that you will reconsider the proposed regulatory actions.

Please feel free to call if you have any questions or concerns.

Sincerely,

Peter D. LeRoux, M.D.

PDL:dm

97N- 4845 C129

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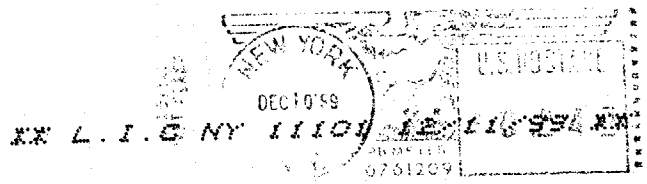

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